

**UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH CAROLINA  
AIKEN DIVISION**

Jeffrey Allen Hesik,	)	Civil Action No.: 1:12-cv-00014-JMC
	)	
Plaintiff,	)	
	)	
v.	)	<b><u>ORDER AND OPINION</u></b>
	)	
Boston Scientific Corporation,	)	
	)	
Defendant.	)	
	)	

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In this products liability action, Plaintiff Jeffrey Allen Hesik (“Plaintiff”) alleges that Defendant Boston Scientific Corporation (“Defendant”) manufactured and sold a defective defibrillator that proximately caused him to suffer severe and permanent injuries. (See ECF No. 11.) Plaintiff asserts causes of action against Defendant for negligence, breach of express warranty, breach of implied warranties, and strict liability. (Id. at 4–6.)

This matter is now before the court on (1) a motion by Plaintiff for summary judgment pursuant to Fed. R. Civ. P. 56 (the “Rule 56 motion”) on his causes of action for breach of express warranty, breach of implied warranties, and strict liability; and (2) a Rule 56 motion by Defendant as to all of Plaintiffs’ claims. (ECF Nos. 69, 70.) For the reasons set forth below, the court **GRANTS IN PART AND DENIES IN PART** Defendant’s Rule 56 motion and **DENIES** Plaintiff’s Rule 56 motion.

**I. RELEVANT FACTUAL BACKGROUND TO THE PENDING MOTIONS**

On January 6, 2009, Plaintiff was admitted to the Aiken Regional Medical Center in Aiken, South Carolina to receive a new cardiac defibrillator. (ECF No. 11 at 1 ¶ 6.) Plaintiff’s existing defibrillator was replaced with Defendant’s COGNIS Cardiac Resynchronization

Therapy Defibrillator, Model N118, Serial No. 559315 (the “Defibrillator”). (Id. at ¶ 7.) The Defibrillator was manufactured on May 27, 2008, and it had been approved as a Class III medical device by the United States Food and Drug Administration (“FDA”) through the supplemental Pre-Market Approval (“PMA”) process. (ECF No. 70-2 at 3 ¶ 6–4 ¶ 11.) The Defibrillator also was packaged and labeled in compliance with all FDA-approved specifications and processes. (ECF No. 70-3 at 4 ¶ 9.) In addition, the Defibrillator came with a warranty (the “Warranty”) that covered a period of five (5) years after the date of implantation and was available “only if the pulse generator fails to function within normal tolerances due to defects in materials, workmanship, or design during the warranty period . . . .” (ECF No. 69-4.)

On October 30, 2009, the Defibrillator failed. (ECF No. 11 at 2 ¶ 8.) As a result of the Defibrillator’s failure, Plaintiff suffered a complete heart block and atrial fibrillation and had to be transported to Provena St. Joseph Medical Center in Joliet, Illinois. (Id. at ¶ 9.) On October 31, 2009, the Defibrillator was surgically explanted due to a “Product Performance Issue”<sup>1</sup> and replaced. (Id. at ¶ 10; ECF No. 69-1 at 4 (referencing ECF No. 69-5).) Defendant’s Post Market Quality Assurance Laboratory examined the Defibrillator and issued a CRM Complaint Summary Report (the “CRM Report”) explaining the reason for its failure as follows:

Upon receipt at our Post Market Quality Assurance laboratory, external visual inspection noted that the device case was swollen. There was blood in the atrial seal plug cavity and lead barrel. The end of the antenna housing was deformed and bubbled. All seal plugs are intact and all set screws operated normally. This is a version 1 header. An x-ray was performed and found damage at the cell terminal connection area. The pulse generator case was removed and internal visual inspection noted heat damage to the cell, hybrid and framework. Any evidence of the cause of this damage was destroyed.

(ECF No. 69-6.) Thereafter, on December 1, 2009, Defendant issued a Physician Device Advisory Notice (the “PDA Notice”), which notice advised medical personnel that listed models

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<sup>1</sup> This description was set forth in a form titled CRT-D Warranty Validation and Lead Registration (the “CRT-D Form”).

including the Defibrillator may experience performance failure and that the root cause is a “[w]eakened bond between the header and case.” (ECF No. 69-7.) After conducting the examination of the Defibrillator, Defendant gave a credit of \$25,056.00 to Provena St. Joseph Medical Center pursuant to the Warranty on the Defibrillator and sent Plaintiff a check for \$2,500.00 to help offset unreimbursed medical expenses remaining from his defibrillator replacement surgery in accordance with its Unreimbursed Medical Expense Program. (See ECF Nos. 69-3, -9, -10.)

On November 21, 2011, Plaintiff filed suit against Defendant in the Aiken County (South Carolina) Court of Common Pleas alleging claims for negligence (Count 1), strict liability pursuant to S.C. Code Ann. § 15-73-10 (1976) (Count 2), and breach of express and implied warranties (Count 3). (See ECF No. 1-1.) On January 3, 2012, Defendant removed the matter to this court on the basis of diversity jurisdiction pursuant to 28 U.S.C. §§ 1332, 1441 and 1446. (ECF No. 1.) In response to the allegations in the complaint, Defendants filed a motion on January 10, 2012, seeking dismissal of the complaint under Fed. R. Civ. P. 12(b)(6) due to Plaintiff’s failure to state a claim. (ECF No. 8.) Plaintiff then amended his complaint on January 31, 2012, to allege claims for negligence (Count 1), breach of express warranty (Count 2), breach of implied warranties (Count 3), and strict liability pursuant to S.C. Code Ann. § 15-73-10 (1976) (Count 4). (ECF No. 11.) Defendant filed a motion to dismiss the amended complaint for failure to state a claim on March 1, 2012, which motion was denied by the court on November 16, 2012. (ECF Nos. 13, 25.)

On October 3, 2013, the court entered an amended conference and scheduling order that bifurcated discovery in this case into two (2) phases. (ECF No. 50.) The first phase of discovery closed on April 25, 2014, and was limited to the issue of whether Plaintiff’s claims are preempted by federal law. (Id. at 1-3.) Therefore, in accordance with the court’s amended

scheduling order, Plaintiff and Defendant filed cross motions for summary judgment on May 22, 2014 and May 23, 2014, respectively. (ECF Nos. 69, 70.) Moreover, each party filed a response in opposition to the other's Rule 56 motion on June 23, 2014. (ECF Nos. 74, 75.)

On September 29, 2014, the court held a hearing on the pending Rule 56 motions. (ECF No. 81.)

## **II. LEGAL STANDARD AND ANALYSIS**

### **A. Summary Judgment Generally**

Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if proof of its existence or non-existence would affect the disposition of the case under the applicable law. Anderson v. Liberty Lobby Inc., 477 U.S. 242, 248–49 (1986). A genuine question of material fact exists where, after reviewing the record as a whole, the court finds that a reasonable jury could return a verdict for the non-moving party. Newport News Holdings Corp. v. Virtual City Vision, 650 F.3d 423, 434 (4th Cir. 2011).

In ruling on a motion for summary judgment, a court must view the evidence in the light most favorable to the non-moving party. Perini Corp. v. Perini Constr., Inc., 915 F.2d 121, 123–24 (4th Cir. 1990). The non-moving party may not oppose a motion for summary judgment with mere allegations or denials of the movant's pleading, but instead must "set forth specific facts" demonstrating a genuine issue for trial. Fed. R. Civ. P. 56(e); see Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986); Shealy v. Winston, 929 F.2d 1009, 1012 (4th Cir. 1991). All that is required is that "sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." Anderson, 477 U.S. at 249. "Mere unsupported speculation . . . is not enough to defeat a summary judgment motion." Ennis v. Nat'l Ass'n of

Bus. & Educ. Radio, Inc., 53 F.3d 55, 62 (4th Cir. 1995).

B. Products Liability Generally

Under South Carolina law, a plaintiff may bring a products liability claim under several theories, including negligence, strict liability, and breach of warranties, as Plaintiff has done in this case. Talkington v. Atria Reclamelucifers Fabrieken BV (Cricket BV), 152 F.3d 254, 261 (4th Cir. 1998) (stating that South Carolina appellate courts have consistently recognized this general proposition) (citations omitted). Regardless of the theory upon which the plaintiff chooses to base his cause of action, he must always establish the following elements: “(1) that he was injured by the product; (2) that the product, at the time of the accident, was in essentially the same condition as when it left the hands of the defendant; and (3) that the injury occurred because the product was in a defective condition unreasonably dangerous to the user.” Talkington, 152 F.3d at 262 (quoting Bragg v. Hi-Ranger, Inc., 462 S.E.2d 321, 326 (S.C. 1995)).

C. The Parties Arguments in Support of Their Rule 56 Motions

1. *Plaintiff*

Plaintiff argues that he is entitled to summary judgment as to his second and third causes of action for breach of express warranty and breach of implied warranties because Defendant provided Provena St. Joseph Medical Center with a credit of \$25,056.00 pursuant to the Defibrillator’s Warranty and gave Plaintiff \$2,500.00 for unreimbursed medical expenses, which actions support a finding as a matter of law that the Defibrillator failed due to a defect that was covered under the Warranty. (ECF No. 69-1 at 3, 6-7.) In support of this argument, Plaintiff asserts that these payments were made only after Defendant’s quality assurance technicians thoroughly examined the Defibrillator thereby precluding Defendant from arguing that the Defibrillator did not possess a “defect[]in materials, workmanship, or design.” (Id. at 7.)

Plaintiff further asserts that because Defendant provided an express warranty, South Carolina law presumes that he as a recipient of the Defibrillator is a third party beneficiary of the Warranty and any attempt by Defendant to disclaim liability for consequential damages is ineffective. (*Id.* at 8–9 (citing S.C. Code Ann. § 36-2-318 (2003) (“A seller’s warranty whether express or implied extends to any natural person who may be expected to use, consume or be affected by the goods and whose person or property is damaged by breach of the warranty. A seller may not exclude or limit the operation of this section.”)).) Additionally, Plaintiff argues that he is entitled to summary judgment on his strict liability claim because the examination results of the Defibrillator by Defendant’s quality assurance technicians create an inference that the Defibrillator was defective and unreasonably dangerous “due to defects in materials, workmanship, or design.” (*Id.* at 10 (citing S.C. Code Ann. § 15-73-10 (1976)).)

## *2. Defendant*

Defendant argues that it is entitled to summary judgment on all of Plaintiff’s claims because they are preempted by federal law. (ECF No. 70-1 at 2.) Specifically, Defendant argues that Plaintiff’s claims for injuries resulting from the Defibrillator are preempted by the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301–399f, as explained by the United States Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). (*Id.*) In support of this argument, Defendant asserts that the FDA classified the Defibrillator as a Class III medical device and Plaintiff’s claims directly attack the Defibrillator’s design, construction, manufacturing methods, testing, and labeling of the device at issue, all of which were specifically approved by the FDA pursuant to an equivalent of that agency’s most rigorous PMA process. (*Id.* (referencing ECF No. 70-2 at 7–13).)

Defendant further argues that Plaintiff is unable to establish a “parallel claim” exception that would allow his claims to avoid preemption. (*Id.*) Referencing Plaintiff’s responses to its

discovery requests, Defendant asserts that “the documents on which Plaintiff relies do not support a parallel claim because they (1) apply to unrelated devices, (2) include information on the issue that Plaintiff’s Model N118 device had without any mention of a violation of a federal requirement, or (3) actually demonstrate that there is no federal violation associated with Plaintiff’s device at issue.” (*Id.*) Defendant further asserts that Plaintiff’s sole basis for a parallel claim relates to two late-reported manufacturing changes<sup>2</sup>, which are unrelated to Plaintiff’s alleged injuries because both changes were made after Plaintiff’s device was manufactured and neither change bears any relationship to Plaintiff’s vague allegations of battery or “processor” failures, or the safety of the device in general. (*Id.* at 19.) Finally, Defendant contends that because Plaintiff has not presented any evidence of a federal violation connected to the Defibrillator, his parallel claim theory is without merit. (*Id.* at 21.) Therefore, Defendant requests that the court enters summary judgment in its favor and dismiss Plaintiff’s entire case with prejudice. (*Id.*)

#### D. The Court’s Review

##### 1. *Statutory and Regulatory Background*

Plaintiff agrees that the Defibrillator was a Class III medical device under the Medical Device Amendments of 1976 (“MDA”), 21 U.S.C. §§ 360c–360k. (See, e.g., ECF No. 11 at 2 ¶ 14 (“The COGNIS N118 CRT-D defibrillator is a Class III medical device as designated by the FDA.”).) Congress enacted the MDA to the FDCA to redefine the term “medical device” and create a system for classification and premarket clearance of medical devices. The MDA grouped all medical devices into one (1) of three (3) regulatory classes based on the controls necessary to provide reasonable assurance of each device’s safety and effectiveness. 21 U.S.C. §

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<sup>2</sup> Defendant submitted two (2) manufacturing changes to its COGNIS line of products to the FDA in February and April 2009. (ECF No. 70-3 at 4 ¶¶ 11, 12.) Both manufacturing changes were approved by the FDA on April 15, 2010. (*Id.* at ¶ 13.)

360c(a)(1)(A)–(C). Class I devices, which carry the least risk, are governed solely by the general misbranding and adulteration controls of the FDCA and its implementing regulations. Id. at § 360c(a)(1)(A). Class II devices present a greater risk than Class I devices, and thus Class II devices must comply with both the general controls governing Class I devices and special controls designed to assure safety and effectiveness. Id. at § 360c(a)(1)(B). Class III devices present a greater risk than Class I and Class II devices, and therefore require PMA, a scientific review conducted by the FDA to ensure the device’s safety and effectiveness. Id. at § 360c(a)(1)(C). “In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is ‘purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,’ or ‘presents a potential unreasonable risk of illness or injury.’” Riegel, 552 U.S. at 317 (citing 21 U.S.C. § 360c(a)(1)(C)(ii)).

PMA is based on a determination by the FDA that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. 21 C.F.R. § 814.2(a). PMA “is a rigorous process,” which involves an extensive application, disclosure of all investigations related to the device’s safety and effectiveness, disclosure of all ingredients or device components, review of manufacturing processes and facilities, submission of device samples, and submission of device labeling. Walker v. Medtronic, Inc., 670 F.3d 569, 572–73 (4th Cir. 2012) (citing Riegel, 552 U.S. at 317; 21 U.S.C. § 360e(c)(1)). “Once a [Class III] device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness.” Riegel, 552 U.S. at 319.

“The FDA continues to oversee Class III devices [even] after the grant of premarket approval.” Walker, 670 F.3d at 574. Device manufacturers are subject to continued reporting requirements, “including the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device of which the manufacturer knows or reasonably should know of,” and the obligation “to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it reoccurred.” Riegel, 552 U.S. at 317 (citing 21 U.S.C. § 360i(a)(1)). Moreover, “[t]he FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling.” Riegel, 552 U.S. at 319–20 (citing 21 U.S.C. § 360e(e)(1)).

## 2. *Preemption*

As a means of creating uniform federal regulations, the MDA included an express preemption provision, which provides in relevant part:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). This clause generally bars common law tort claims against Class III device manufacturers, because those claims seek to impose different or additional requirements for purposes of § 360k(a). See Riegel, 552 U.S. at 322–25; see also Walker, 670 F.3d at 577. In Riegel, the Supreme Court announced a two-prong test to determine whether a state law claim is expressly preempted under § 360k: (1) whether the federal government has established requirements applicable to the medical device, and (2) if so, whether the state law claim would impose requirements that are “different from or in addition to” the federal requirements. Riegel,

552 U.S. at 321–22. Medical devices that have received PMA automatically satisfy the first prong. See id. at 328. As to the second prong, the Supreme Court held the following:

State requirements are pre-empted under the MDA only to the extent that they are “different from, or in addition to” the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case “parallel,” rather than add to, federal requirements.”

Id. at 330.<sup>3</sup>

This provision regarding parallel duties provides the one narrow exception to the rule of preemption. A plaintiff may bring claims directly against a device manufacturer if the state law claims parallel federal law, *i.e.*, do not impose requirements that are different from, or in addition to, those already imposed on the manufacturers by federal law. A well-pleaded parallel claim must at least (1) identify the federal requirement applicable to the device with which it allegedly failed to comply and (2) explain how that violation of a federal requirement caused the plaintiff’s injury. See, e.g., Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div., Civil Case No. CCB-12-1746, 2013 WL 1104427, at \*4 (D. Md. Mar. 13, 2013); Ali v. Allergan USA, Inc., No. 1:12CV115, 2012 WL 3692396, at \*8 (E.D. Va. Aug. 23, 2012); Viserta v. St. Jude Med., Inc., C.A. No. 8:11CV505, 2012 WL 667814, at \*4 (D.S.C. Feb. 29, 2012); Bishoff v. Medtronic Inc., Civil Action No. 1:09CV171, 2010 WL 4852650, at \*2 (N.D. W. Va. Nov. 22, 2010); Covert v. Stryker Corp., No. 1:08CV447, 2009 WL 2424559, at \*14–15 (M.D.N.C. Aug. 5, 2009).

In addition to Plaintiff’s express agreement that the Defibrillator was a Class III medical device, there also does not appear to be a dispute about whether the FDA approved the design, manufacturing process, and labeling of the Defibrillator as appropriate and reasonably safe pursuant to a PMA process under the MDA. (See, e.g., ECF No. 11 at 2 ¶ 13 (“After the model

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<sup>3</sup> However, the Supreme Court stopped short of specifying what a plaintiff must show to properly plead a “parallel” claim because the plaintiffs in Riegel did not assert that their claims were parallel. See Riegel, 552 U.S. at 330.

N118 CRT-D defibrillator received premarket approval as required by 21 U.S.C. § 360(e), . . . .”.) Therefore, because the Defibrillator is clearly subject to federal requirements, Plaintiff’s claims for negligence, breach of express warranty, breach of implied warranties, and strict liability are preempted, unless they are parallel claims to the federal requirements.

*3. Preemption in the Context of Plaintiff’s Particular Claims*

In opposing preemption of his causes of action, Plaintiff argues that the parallel claims exception applies to his claims based on Defendant’s admission that the Defibrillator was defective “in materials, workmanship, or design” and such admission establishes that the Defibrillator was not manufactured as represented to and approved by the FDA in the PMA. (ECF No. 74 at 7–8; see also ECF No. 11 at 3 ¶¶ 16–19.) In support of this argument, Plaintiff asserts that the Defibrillator was different from the medical device that received PMA approval because the Defibrillator was not hermetically sealed as was represented to the FDA in the PMA. (ECF No. 74 at 2.) As evidence of this defect in the Defibrillator, Plaintiff points to findings in a Hazard Analysis Report<sup>4</sup>, the CRT-D Form, the CRM Report, the PDA Notice, and the memo providing the credit to Provena St. Joseph Medical Center. (ECF Nos. 69-3, 69-5, 69-6, 69-7, 69-9.)

Plaintiff further argues that the parallel claims exception is applicable because Defendants violated federal regulations by manufacturing a medical device that failed to stimulate his heart and by providing a warranty that was untruthful, inaccurate, and misleading in violation of the uniform commercial code. (ECF No. 74 at 8–9 (citing 21 C.F.R. §§ 870.3610, 808.1(d)(1))).) In support of his arguments, Plaintiff cites to Easterling v. Cardiac Pacemakers,

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<sup>4</sup> The Hazard Analysis Report contains statements that battery swelling is a hazard that is mitigated by “[c]ell performance proven to meet requirements” and “non-hermetic battery and ineffective laser weld of cases or feedthru assembly” is a hazard mitigated by “cells [that] are 100% inspected for hermeticity after case welding” or “cells [that] are 100% inspected for electrolyte leakage after laser sphere weld.” (ECF No. 69-3.)

Inc., 986 F. Supp. 366 (E.D. La. 1997), in which the court stated that claims could survive preemption where they are based on the manufacturer's "failure to adhere to the standards set forth by the FDA in the PMA." Id. at 375.

Defendant maintains that all of Plaintiff's claims are expressly preempted under Riegel. (ECF No. 75 at 9.) Because the Defibrillator was a Class III medical device that had passed through the PMA process, the issue of preemption turns on the second step of the Riegel analysis. In this regard, the court considers below whether each of Plaintiff's claims imposes requirements that are "different from, or in addition to" the requirements imposed by federal law.

#### **a. Negligence**

In South Carolina, a manufacturer has the duty to use reasonable care throughout the manufacturing process, including making sure the product is free of any potentially dangerous defect in manufacturing or design. Jackson v. Bermuda Sands, Inc., 677 S.E.2d 612, 614–15 (S.C. Ct. App. 2009) (citing Rife v. Hitachi Constr. Mach. Co., Ltd., 609 S.E.2d 565, 569 (S.C. Ct. App. 2005)). Plaintiff alleges that the Defibrillator was negligently manufactured because the actual manufacture of the device deviated from the specifications required by the PMA.

Upon review, the court agrees with Plaintiff that if the Defibrillator did not conform to the PMA's specifications, then he would have a parallel claim to avoid preemption. See, e.g., Bass v. Stryker Corp., 669 F.3d 501, 515 (5th Cir. 2012) (finding that plaintiff's manufacturing defect claims could proceed because they were premised on violations of FDA regulations and therefore parallel claims that were not preempted); Riegel v. Medtronic, Inc., 451 F.3d 104, 123–24 (2d Cir. 2006) ("By the same token, we agree with the district court's conclusion that the Riegels' negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards. A jury

verdict in the Riegels' favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards."); Williams v. Cyberonics, Inc., 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009) ("To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards."). However, the court finds that a parallel claim of negligence does not exist in this case because Plaintiff has failed to offer any evidence that creates a genuine issue of material fact as to how the Defibrillator deviated from the PMA's specifications. Plaintiff failed to submit any evidence to substantiate his claim that the Defibrillator had lost its hermetic seal, and is further unable to contradict Defendant's affidavit from its Site Compliance Advisor who declared that the explanted Defibrillator "showed no evidence that the device lost its hermetic seal." (ECF No. 75-1 at 5 ¶ 14.) Moreover, the documents cited by Plaintiff do not demonstrate the existence of a deviation from the PMA's specifications. As plaintiff has not offered any actual proof of a specific manufacturing deviation from the Defibrillator's specifications required by the PMA, Plaintiff is unable to establish his parallel claim for negligence. Accordingly, the court must conclude that Plaintiff's claim for negligence is preempted.

#### **b. Strict Liability**

The theory of strict liability is premised on the concept that the cost of injuries resulting from defective products should be borne by the manufacturer or seller who puts such products on the market rather than by the ultimate users who are injured by the product and powerless to protect themselves. Fleming v. Borden, Inc., 450 S.E.2d 589, 592 (S.C. 1994). The court finds that for the same reasons that Plaintiff's negligence claim is preempted, his strict liability claim premised on the Defibrillator's alleged deviation from the requirements of the PMA is also preempted. That is, Plaintiff has not put forth any evidence to establish how Defendant's

manufacture of the Defibrillator deviated from the requirements of its PMA.

### **c. Breach of Express Warranty and Implied Warranties**

Generally, the failure of a product to work as expected or represented is sufficient to give rise to an inference of breach of warranty. Se. PVC Pipe Mfg. v. Rothrock Constr. Co., 313 S.E.2d 50, 52 (S.C. 1984); Simmons v. CIBA-GEIGY Corp., 302 S.E.2d 17, 18 (S.C. 1983). The South Carolina Commercial Code establishes three types of warranty: (1) implied warranty of merchantability<sup>5</sup>; (2) implied warranty of fitness for a particular purpose<sup>6</sup>; and (3) an express warranty.<sup>7</sup> In an action based on warranty, plaintiff's case is complete when he has proved the product, as designed, was in a defective condition unreasonably dangerous to the user when it left the control of the defendant, and the defect caused his injuries. Madden, 328 S.E.2d at 112 (citing S.C. Code Ann. § 15-73-10).

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<sup>5</sup> “Unless excluded or modified . . . , a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.” S.C. Code Ann. § 36-2-314(1) (2003). South Carolina law sets forth several requirements that must be met for goods to be merchantable. Id. at § 36-2-314(2). Goods are merchantable when they “are fit for the ordinary purposes for which such goods are used.” Id.

<sup>6</sup> In South Carolina, an implied warranty of fitness for a particular purpose arises if “the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods . . . .” S.C. Code Ann. § 36-2-315 (2003). If “the particular purpose for which a product is purchased is also the ordinary or intended purpose of the product, the warranties of merchantability and of fitness for a particular purpose merge and are cumulative, such that a plaintiff may proceed upon either theory.” Soaper v. Hope Indus., 424 S.E.2d 493, 495 (S.C. 1992) (holding that plaintiff, who purchased film processing machine, “impliedly made known to [defendant] that his particular purpose for the machine was fast film processing” and that “[w]hen the machine failed in that purpose, it was both unmerchantable and unfit for its particular purpose”).

<sup>7</sup> In South Carolina, a seller may create an express warranty in a number of ways, including “[a]ny affirmation of fact or promise, . . . made by the seller to the buyer, whether directly or indirectly, which relates to the goods and becomes part of the basis of the bargain.” S.C. Code Ann. § 36-2-313(1) (1976). In addition, “[a]ny description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.” Id. In order to establish a cause of action for breach of an express warranty, a plaintiff must show “the existence of the warranty, its breach by the failure of the goods to conform to the warranted description, and damages proximately caused by the breach.” First State Sav. & Loan v. Phelps, 385 S.E.2d 821, 825 (S.C. 1989).

Plaintiff alleges that Defendant breached the implied warranties of merchantability and fitness for a particular purpose by manufacturing the Defibrillator, which failed after less than one (1) year, and that this breach caused his injuries. (ECF No. 11 at 5 ¶¶ 36, 37.) Implied warranties are “centered around the accepted standards of design and manufacture of products” in the state in which the warranties originate. See, e.g., Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004). However, the FDA has already provided federal requirements relating to the design and manufacture of the Defibrillator through the PMA process. “As an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, [such claims] . . . impose a requirement additional to those imposed under the MDA.” King v. Collagen Corp., 983 F.2d 1130, 1137 (1st Cir. 1993). Therefore, the court concludes that Plaintiff’s implied warranties claim is expressly preempted by the MDA, and summary judgment as to the implied warranties claim is appropriate. Riegel, 552 U.S. at 330 (holding that implied-warranty claim preempted).

Plaintiff asserts in his breach of express warranty claim that Defendant expressly warranted that the Defibrillator’s pulse generator “would function without failure because of defects for a period of five (5) years.” (ECF No. 11 at 5 ¶ 31.) Defendant argues that this claim is preempted, that the warranty was not the basis of the bargain, and that it has already fulfilled its warranty obligations. After reviewing the contents of the Warranty and the authority cited by both parties, the court concludes that Plaintiff’s express warranty claim is not preempted.

If Plaintiff’s breach of express warranty claim were premised on any statements made in a FDA-mandated document, the claim would be preempted. Here, however, Plaintiff’s breach of express warranty claim is premised solely on Defendant’s alleged voluntary statements in the Warranty, which statements have not been established as subject to the PMA process or otherwise approved or mandated by the FDA. In this regard, the court’s recognition of

Plaintiff's breach of express warranty claim presents no risk of interference with the federal medical device regulatory scheme, and the claim escapes express preemption under Section 360k(a). Therefore, the court denies Defendant's Rule 56 motion on preemption grounds as to Plaintiff's breach of express warranty claim. See, e.g., Riley v. Cordis Corp., 625 F. Supp. 2d 769, 788 (D. Minn. 2009) ("[A] a breach-of-express-warranty claim based on voluntary statements is not preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer need do nothing more than refrain from making voluntary warranties.").

#### **d. Claims Premised on the Violation of Regulations**

Plaintiff attempts to create a parallel claim by alleging violation of two (2) federal regulations. The first regulation that Plaintiff cites states that "[a]n implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart." 21 C.F.R. § 870.3610. The second regulation provides that "[s]ection 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. §808.1(d)(1).

After reviewing the content of these regulations, the court is not persuaded that Plaintiff has stated a parallel claim that avoids preemption.<sup>8</sup> First, the court notes that neither regulation refers specifically to the medical device at issue. Second, the regulations do not provide any kind of tangible or concrete standard, and "to allow a violation of . . . a flexible standard to result in liability would, in itself, be imposing a standard 'different from, or in addition to' those

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<sup>8</sup> The court notes that the Plaintiffs in Riegel also argued that their claims were not preempted because of § 808.1(d)(1). The Supreme Court rejected this argument concluding that the regulation failed to alter the Court's interpretation of § 360k(a). Riegel, 552 U.S. at 329–30.

imposed by the MDA.” Horn v. Boston Scientific Neuromodulation Corp., No. CV409–074, 2011 WL 3893812, at \*9 (S.D. Ga. Aug. 26, 2011) (citing 21 U.S.C. § 360k(a)(1)). Accordingly, where a plaintiff relies on nothing more than unsupported violations of general regulations in support of a parallel cause of action, preemption bars the claim. Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009).

### III. CONCLUSION

For the foregoing reasons, the court **GRANTS IN PART AND DENIES IN PART** the motion for summary judgment of Defendant Boston Scientific Corporation. (ECF No. 70.) The following claims are preempted and dismissed with prejudice: negligence, strict liability, breach of implied warranties, and any claims premised on a violation of 21 C.F.R §§ 870.3610, 808.1(d)(1). The court further **DENIES** the motion for summary judgment of Plaintiff Jeffrey Allen Hesik. (ECF No. 69.) The court directs the parties to proceed with Phase II of Discovery in relation to Plaintiff’s remaining claim for breach of express warranty as contemplated by the amended conference and scheduling order. (See ECF No. 50.)

**IT IS SO ORDERED.**



United States District Judge

November 4, 2014  
Columbia, South Carolina